UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,760	12/08/2003	John A. Dyjach	279.663US1	3450

21186 7590 05/06/2005

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402-0938

EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/730,760	DYJACH ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *1-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-26-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1–28, drawn to a method, classified in class 600, subclass 513.

II. Claims 29–60, drawn to a device and system, classified in class 607, subclass 9.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I (process) and Group II (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus or by hand not involving a memory embedded with computer instructions, but rather custom logic circuitry.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Marvin Beekman on Monday, May 02, 2005 a provisional election was made without traverse to prosecute the invention of Group II, claims 29 – 60. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 1 – 28 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: On page 15, the end of the sentence "This mode of pacing ... chamber reaches the other" (lines 26–29) is unclear. It appears that some words should be added and modified after the word "chamber" (line 29).

On page 25, it appears that the word "non-tracing" (line 16) should be "non-tracking."

On page 28, the sentence "Various embodiments process ... in the CRM device" (lines 23–24) is also unclear. It too appears to be missing a word after the word "device" (line 24). In looking at the sentences that precede and follow this sentence, adding the word "and" after the word "device" word make the sentence clear.

On page 31, should the word "simply" (line 1) be "simplify?"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 29–60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29, "plurality of electrodes" (line 2), "at least one lead" (line 3), cardiac resynchronization therapy (CRT)" (line 6), "CRT-related data" (line 10), "a status" (line 10), and an external device" (lines 12–13) are inferentially included. It cannot be determined if these elements are being positively recited or functionally recited. To positively claim the elements, it is suggested to first positively recite the elements. Otherwise, functional language such as "for" or "adapted to be" should be used. In addition, "the pacing pulses" (line 9) is inferentially included and vague. The pacing pulses have only been functionally recited. It is suggested to use "adapted to control."

In claim 49, "a prescribed cardiac resynchronization therapy (CRT)" (line 2) and "a status of" (lines 13–14) are inferentially included. Further, "a prescribed cardiac resynchronization therapy (CRT)" (lines 3–4) is vague. Should it be "the prescribed cardiac resynchronization therapy (CRT)" given that the limitation is introduced in the preamble of the claim? Additionally, "the pacing pulses" (line 12) is inferentially included and vague. The pacing pulses have only been functionally recited. It is suggested to use "adapted to control." Also, "trended data samples" (line 30) make the claim incomplete for not setting forth an element to trend the data samples.

In claim 54, "plurality of electrodes" (lines 4–5) and " a status"(line 10) are inferentially included. In addition, "means to" (lines 12, 15, and 18) is vague since it is unclear if Applicant is invoking 35 U.S.C. 112 sixth paragraph. 35 U.S.C. 112 sixth paragraph must use "means for"

language. Further, "trended data" (line 18) make the claim incomplete for not setting forth an element to trend data.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 29–30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroeppel et al., U.S. Patent 5,749,900.

Schroeppel discloses an implantable cardiac rhythm management (CRM) device, a plurality of interface channels, a plurality of electrodes on at least one lead, a memory, a controller, and a communication circuit (Fig. 1; column 5, lines 12–67; column 6, lines 1–39; column 7, lines 21–23); chronic, ambulatory data (column 6, lines 26–31).

11. Claims 29–52, 54–55, 58–60 are rejected under 35 U.S.C. 102(b) as being anticipated by Stahmann et al., U.S. Patent 6,480,742.

Stahmann discloses an implantable cardiac rhythm management (CRM) device, a plurality of interface channels, a plurality of electrodes on at least one lead, a memory, a controller, a communication circuit, a programmer, a monitor, a right ventricle interface channel, a left ventricle interface channel, a right atrium interface channel (Fig. 1; column 3, lines 35–67; column 4, lines 1–11); chronic, ambulatory data/status (column 3, lines 7–11 and 13–17); the

controller is adapted to do the following in or to the memory: record prescribed CRT data and time information, record realized CRT data and time information, record a pacing mode and time information, record when the device is operating in an atrial tracking mode, trend samples or CRT-related data relevant to the status of the prescribed CRT (including to trend N samples per unit time, N samples per unit time until a predetermined change occurs in or threshold is reached related to delivered CRT or a predetermined event occurs and then trend M samples per unit time, to trend M samples per unit time after initiation of trigger, to trend a first parameter before a trigger and a second parameter after the trigger), a value corresponding to CRT delivery, ventricular pacing, atrial tachycardia, capture, a value above a programmed above a programmed rate, a mode of operation, and a CRT delivery results and each value being at least from a group consisting of a percentage value and an absolute value (Figs. 1–5; column 2, lines 25–36; column 3, lines 37–42; column 5, lines 11–12; column 6, lines 5–28; column 9, lines 45–66; column 10 lines 4–58; column 11; column 12).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann as applied to claim 49 above, and in view of Schroeppel et al., U.S. Patent 5,749,900.

Stahmann does not disclose an alert corresponding to the status of the prescribed CRT. However, Schroeppel discloses an alert corresponding to the status of the prescribed CRT (column 9, lines 17–22) to communicate a patient's pending heart condition (column 9, lines 19–20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stahmann to include an alert corresponding to the status of the prescribed CRT, as taught by Schroeppel to communicate a patient's pending heart condition (column 9, lines 19–20).

14. Claims 56–57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann U.S. Patent 6,480,742.

Stahmann discloses a means to display information (Fig. 1) but he does not disclose a graph or table of the trended data. However, it is common knowledge in the art that a graph and table can be used to display trended data because the format can be easily read and understood by a patient, clinician, healthcare provider, or physician.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stahmann to include a graph or table of the trended data because the format can be easily read and understood by a patient, clinician, healthcare provider, or physician.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
May 4, 2005
4 May 2005

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/4/5